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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William N. Borkan

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08/15/2006

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EXAMINER

GEDEON, BRIAN T

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/712,053	Applicant(s) BORKAN, WILLIAM N.	
	Examiner Brian T. Gedeon	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13 is/are allowed.
- 6) ☒ Claim(s) 1-6, 14-17 and 19-24 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. New claim 24 depends on claim 7, and is a duplicate of claim 11, also depending from claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5, 6, 14, 15, 17-20, 22, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Vaiani et al. (US Patent no. 5,374,285) in view of Quinn et al. (US Patent no. 6,036,654).

In regard to claims 1, 5, 19 and 22, Vaiani et al. discloses an electrode catheter for inserting near the spinal column (i.e., intrathecal space), col 3 lines 13-20. The catheter comprises a tubular sheath 1 with an electrode P, col 3 lines 21-30. The sheath has an open central passage, which has a diameter large enough to allow a fixation stylet through, col 3 lines 53-58. Quinn et al. discloses a multi-lumen, multi-parameter catheter that is capable of pacing the heart (i.e., delivering electrical therapy)

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and drug infusion, col 1 lines 14-19 and 43-51. The catheter 10 comprises a flexible catheter tube 12 that inherently comprises a proximal end and a distal end. The distal end of the catheter 10 has an inflatable balloon 32 allowing for ease of implantation as well as anchoring. The catheter has a plurality of lumens, col 3 lines 29-35, of which one is a fiber optic lumen 24 to house optic fibers, col 4 lines 21-24. The Examiner contends that the lumen is an open passage and inherently comprises an inlet and an outlet. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Vaiani et al. with Quinn et al. design a multi-lumen stimulation catheter for undertaking therapeutic operations such as drug infusion or using fiber optics photonic light therapy.

In regard to claim 2, Vaiani et al. describes the claimed invention except for anchor at the distal end. Quinn et al. describes the distal end of the catheter 10 with an inflatable balloon 32. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to anchor the distal end of a catheter with an inflatable balloon since it was well known the art at the time.

In regard to claims 3, 6, 20, and 23, Vaiani et al. discloses a catheter with holes 15 at the distal end 1a so as to permit the infusion of drugs into the region.

3. Claims 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaiani et al. (US Patent no. 5,374,285) in view of Deletis et al. (US Patent no. 5,081,990), further in view of King (US Patent no. 4,630,611).

In regard to claims 14, 15, 17, and 24, Vaiani et al. discloses an electrode catheter for inserting near the spinal column (i.e., intrathecal space), col 3 lines 13-20.

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The catheter comprises a tubular sheath 1 with an electrode P, col 3 lines 21-30. The sheath has an open central passage, which has a diameter large enough to allow a fixation stylet through, col 3 lines 53-58. Vaiani et al. is also equipped with holes 15 for administering therapeutic drugs. Deletis et al. presents a catheter for spinal epidural injection of drugs and measurement of evoked potentials. The catheter inherently possesses a distal end and a proximal end, as depicted in figure 1. The distal end has a plurality of electrodes 12, 13, and 14, which lie along. Passage 31 is adapted to be fitted with a stylet to aid in directing the device for optimal placement, col 3 lines 43-45. The catheter includes another passage 32 located at the proximal end and leads to one or more outlets 11, col 3 lines 49-53, for dispensing medication. Relocation of outlets 11 along the catheter, to the distal end, would be obvious to one of ordinary skill in the art since it has been held that rearranging parts of the involves only routine skill in the art, *In re Japiske*, 86 USPQ 70. King shows a body implantable lead 30, with electrode pairs 34 and 36 near the distal. Figure 2 shows these electrode pairs separated by in degrees around the curvature of the lead. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to embody a catheter in this manner so provide electrical and pharmacological therapy to a desired area of the spinal cord.

Further, in regard to claims 14, 15, and 17, the claimed method would be obvious in view structure set out by the structure recited by the above combine references.

In regard to claim 24, Vaiani et al. in view of Deletis et al. substantially describe the invention as claimed, except for the degree of extension around the surface of the

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lead body. Figure 2 of King shows electrodes 34 and 36 on the distal end of lead body 30. Here the electrodes 34 and 36 are separated by 180 degrees. However the Examiner contends that it would have been obvious to adjust spacing between electrodes to achieve different degrees of separation, and it would have been obvious as well to increase the surface size of the electrode to increase the degree of extension about the lead body and thereby decreasing the amount of separation in degrees between the electrodes.

Allowable Subject Matter

4. Claims 7-13 are allowed. The following is an examiner's statement of reasons for allowance: The prior art disclosed fails to teach alone, or in combination, the use of an extension wire with an additional electrode emanating from the tip of the distal end of the catheter. Therefore the Examiner deems independent claim 7 and its depending claims allowable over the prior record.

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

5. The new grounds of rejection necessitated by the amendment effectively make this action **FINAL**.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Konings (US Patent no. 6,236,879) and Tjin (US Patent no. 6,166,806) both disclose fiber optic catheters. Mackey (US Patent no. 5,423,877) shows electrodes mounted on the distal end of an implantable lead, and extending several degrees about the exterior of the lead surface. Gelinas et al. (US Patent no. 4,522,212) shows an endocardial electrode with wire springs on the distal end.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon
Patent Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG